

## MEDICAL DEVICES – STATEMENT OF INTENT

**MEDICAL DEVICES.** Purchasers of the medical device items identified in the Invitation for Bid shall certify and assure in writing that such items(s) will be used or resold only under the conditions specified below:

1. Medical device items are subject to the laws and regulations administered by the Food and Drug Administration (FDA). Provisions of the governing statute, the Federal Food, Drug and Cosmetic Act appear in 21 U.S.C. 331, et.seq. In summary, the Act prohibits the movement in interstate commerce of medical devices that are misbranded or adulterated. The Act authorizes FDA to initiate criminal enforcement proceedings against companies and/or individuals responsible for violations of its provisions. Moreover, the act authorizes FDA to initiate civil proceedings to seize, or enjoin the distribution of such items.

2. It shall also be the responsibility of all purchasers to comply with local, state, or other applicable laws.

3. The following certificate, to be separate attachment to the Invitation for Bid, is required by FDA to purchase the medical device items identified in the invitation.

a. I certify that I am a licensed practitioner and/or other person regularly and lawfully engaged in the manufacture and/or refurbishing of the medical device items identified below. I also certify that prior to sale or use of such devices I will take necessary steps to assure that such devices are not adulterated or misbranded within the meaning of those terms in the Federal Food, Drug, and Cosmetic Act (21 U.S.C.331, et.seq.).

Invitation for Bids Number: \_\_\_\_\_  
Lot Number(s): \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_ (License Number Required) \_\_\_\_\_  
Full Address: \_\_\_\_\_  
Telephone No.: \_\_\_\_\_  
Signature \_\_\_\_\_ Date \_\_\_\_\_

b. Recognizing that Federal Law places stringent restrictions on adulterated or misbranded medical devices (21 U.S.C.331, et.seq.), I certify that I either (1) will sell or otherwise proffer the medical device items identified below only to the persons described in a. above, or (2) will not use those items for their original or usual intended use, or for the other medical use.

Lot Number(s): \_\_\_\_\_  
Print Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Full Address: \_\_\_\_\_  
Telephone No.: \_\_\_\_\_  
Signature \_\_\_\_\_ Date \_\_\_\_\_

False or misleading statements may result in a fine of not more than \$10,000 or imprisonment for not more than five (5) years, or both (18 U.S.C. 1001).

*The undersigned bidder hereby certifies that if awarded a contract under this invitation for bids, the bidder will comply with all applicable Federal, state, and local laws, ordinances, and regulations with respect to the care, handling, storage, shipment, resale, export, or other use of the material hereby purchased. The bidder will hold the United States harmless from and indemnify the United States against any or all debts, liabilities, judgments, costs, demands, suits, actions, or other claims of any nature arising from or incident to the handling, use, storage, shipment, resale, export, or other disposition of the items purchased.*

*The undersigned bidder certifies that he/she is legally licensed to engage in the manufacture, sale, or distribution of medical equipment and proof of his/her license to deal in such materials is furnished with this bid. This certification is made in accordance with and subject to the penalties of Title 18, Section 1001, United States Code, Crime and Criminal procedures.*

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*Name of bidder (print or type)*

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*Medical license/distribution authority*

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*Signature of bidder*

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*Address of bidder (print or type)*